FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, MD
August 5, 2013

AGENDA

The committee will discuss New Drug Application 204441, tolvaptan tablets, submitted by Otsuka Pharmaceutical Company, Ltd for the proposed indication of slowing kidney disease in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (autosomal dominant polycystic kidney disease is a genetic disease that affects the kidney and can lead to kidney failure).

8:00 a.m.	Call to Order Introduction of Committee	**A. Michael Lincoff, MD** Chairperson, Cardiovascular and Renal Drugs Advisory Committee (CRDAC)
8:05 a.m.	Conflict of Interest Statement	**Kristina A. Toliver, PharmD** Designated Federal Officer, CRDAC
8:10 a.m.	Opening Remarks	**Norman Stockbridge, MD, PhD** Director, Division of Cardiovascular and Renal Products (DCaRP), Office of Drug Evaluation I (ODEI), Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**Sponsor Presentations**	**Otsuka Pharmaceutical Company, Ltd**
	Introduction	**Robert McQuade, PhD** Executive VP & Chief Strategic Officer Otsuka Pharmaceutical Development and Commercialization Inc. (Otsuka)
	Autosomal Dominant Polycystic Kidney Disease (ADPKD) Pathophysiology	**Vicente Torres, MD, PhD** Professor of Medicine, Mayo Clinic
	ADPKD Disease Progression	**Arlene Chapman, MD** Professor of Medicine, Emory University
	Efficacy of Tolvaptan in ADPKD	**Frank Czerwiec, MD, PhD** Sr. Director, Global Clinical Development, Otsuka
	Sponsor Response to FDA Comments	**Robert McQuade, PhD**
	Safety of Tolvaptan in ADPKD	**Christopher Zimmer, MD** Sr. Director, Global Clinical Development, Otsuka
	Risk Evaluation/ Mitigation & Net Benefit	**Robert McQuade, PhD**

AGENDA (cont.)

9:50 a.m.	Clarifying Questions to the Presenters	
10:20 a.m.	**BREAK**	
10:35 a.m.	**FDA Presentations**	
	Clinical and Statistical Findings	**John Lawrence, PhD** Biometrics Reviewer Office of Biostatistics/CDER
		Aliza Thompson, MD Clinical Team Leader DCaRP/OND/CDER
	Risk Management	**Kimberly Lehrfeld, PharmD** Drug Risk Management Analyst Division of Risk Management/ Office of Medication Error Prevention and Risk Management/Office of Surveillance and Epidemiology (OSE)/CDER
11:35 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the Committee and Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee and Committee Discussion (cont.)	
5:30 p.m.	**ADJOURNMENT**	